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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HILL, KEVIN KAI	

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,212	KUFE, DONALD W.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *2-4,6,10-12 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5, 7-8, 9, 13 and 15-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Applicant has elected the invention of Group I, claims 1-8, drawn to a method of identifying a compound that inhibits binding of MUC1 to a tumor progressor. Furthermore Applicant elects the species (iv) β-catenin (Claim 5). The election is made without traverse.

Because Applicant did not distinctly and specifically point out the supposed errors in the Group or species restriction requirement, the restriction and election requirement is deemed proper and therefore made final (MPEP § 818).

Response to Amendment

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. MPEP §818.03(b)

Amendments

1. In the reply filed April 12, 2007, Applicant has amended Claim 1, and added new claims, Claims 9-16. To the extent that newly added Claims 10-12 and 14 are drawn to non-elected tumor progressor test agents, said claims are withdrawn from examination.

2. Claims 2-4 and 6 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

3. Claims 1, 5, 7-8, 9, 13 and 15-16 are under consideration.

Priority

4. Applicant's claim for priority under 35 U.S.C. 119(e) or 120 regarding the parent provisional application 60/257,590, filed on December 22, 2000 and provisional application 60/308,307, filed on July 27, 2001 is acknowledged. It is noted that the amendment to the specification filed on December 11, 2003 states: "This application claims priority of U.S. Application No. 10/032,786, filed December 26, **2003** [emphasis added]." According to the Office records, Application No. 10/032,786 was filed December 26, 2001.

The effective priority date of the instant application is granted as December 22, 2000.

Response to Amendment

Applicant has amended the specification to correct the typographical error regarding the filing date of U.S. Application No. 10/032,786.

Information Disclosure Statement

Applicant has filed Information Disclosure Statements on February 25, 2005 and December 19, 2006 that has been considered. The citation AW, Yamamoto et al, of the IDS filed December 19, 2006 has been lined through because the Examiner has already entered this reference into the prosecution history of this application. The signed and initialed PTO Forms 1449 is mailed with this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

5. **The prior rejection of Claims 1, 5 and 7-8 under 35 U.S.C. 112, second paragraph, is withdrawn** because Applicant has amended the claims to provide the correlation between identifying a compound that inhibits the binding of the MUC1 test agent to the tumor progressor test agent with identifying a compound that inhibits the binding of MUC1 to a tumor progressor.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1, 5 and 7 stand rejected under 35 U.S.C. 102(b)** as being anticipated by Yamamoto et al (J. Biol. Chem. 272(19): 12492-12494, 1997).

The claims are drawn to a method of identifying a compound that inhibits binding of MUC1 to a tumor progressor, wherein the tumor progressor test agent is beta-catenin (βctn), and wherein the contacting step occurs in a cell-free system. Applicant contemplates that the method may be performed using isolated MUC1 and tumor progressor test agents (pg 20, line 6, 20-24). The tumor progressor test agent can be immobilized on a solid substrate such as a nylon or nitrocellulose membrane and then exposed to the MUC1 test agent in the presence and absence of the test compound (pg 21, lines 19-24).

Yamamoto et al teach that the MUC1 cytoplasmic domain recognizes both βctn and gamma-catenin (γctn) when tested by immunoprecipitation from cell lysates and in a filter-binding assay, wherein the catenin test agents are bound to a nitrocellulose membrane and incubated in the presence of a GST-MUC1/CD test agent (pg 12493; Figures 1-2). Yamamoto et al also teach that incubation of the MUC1 test agent with the peptide GGSSLSY inhibited the binding of MUC1 to βctn and γctn in the context of the immunoprecipitation and filter-binding assays (pg 12493; Figure 3).

Thus, Yamamoto et al anticipate Claims 1, 5 and 7.

Applicant's Arguments

Applicant argues that the amendment to step (c) of Claim 1, "wherein the test compound is a compound that binds to MUC1" renders the rejection moot.

Applicant's argument(s) has been fully considered, but is not persuasive.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

In the instant case, Applicant has provided no evidence that the peptide GGSSLSY taught by Yamamoto et al does not bind to MUC1.

7. **Claims 1, 5 and 8 stand rejected under 35 U.S.C. 102(b)** as being anticipated by Li et al (Mol. Cell Biol. 18(12): 7216-7224, 1998, * of record in IDS).

The claims are drawn to a method of identifying a compound that inhibits binding of MUC1 to a tumor progressor, wherein the tumor progressor test agent is beta-catenin (βctn), and wherein the contacting step occurs in a cell. The specification does not define the structural metes and bounds of the inhibitory test compound; however, Applicant contemplates that the compound to be identified by the method includes those compounds that inhibit the binding between MUC1 and a tumor progressor, e.g. the instantly preferred embodiment being βctn (pg 27, lines 7-10).

Li et al teach that 293 and HeLa cells transfected with plasmids expressing kinase-active GSK-3β, resulting in significantly decreased interactions between MUC1 and βctn (pg 7219; see also pg 7220, Figure 5).

Thus, Li et al anticipate Claims 1, 5 and 8.

Applicant's Arguments

Applicant argues that the amendment to step (c) of Claim 1, "wherein the test compound is a compound that binds to MUC1" renders the rejection moot.

Applicant's argument(s) has been fully considered, but is not persuasive.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

In the instant case, the instant specification discloses that GSK3β binds to MUC1 (pg 2, lines 6-7). Applicant has provided no evidence that the GSK3β taught by Li et al is patentably distinct from the disclosed GSK3β. In light of the instant disclosure, the burden is placed on Applicant to provide evidence that the GSK3β of Li et al does not bind to MUC1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **Claims 9, 13 and 15-16 are rejected under 35 U.S.C. 103(a)** as being unpatentable over Brent et al (U.S. Patent No. 6,004,746).

Brent et al disclose methods for detecting protein interactions, wherein a first test agent is provided with a candidate interactor, wherein the candidate interactor physically interacts with a protein of interest (col. 6, lines 5-15). wherein the interactor may be an antagonist of the interaction between two interacting proteins. Protein antagonists may be readily identified and isolated using a variation of the invention (col. 7-8), wherein once a protein-protein interaction has been recorded, a candidate antagonist is introduced and the result is measured. Interaction antagonists are useful as models to design simple mimetics (col. 8, lines 7-8). Brent et al disclose

that the inventive method may be performed intracellularly or in cell-free systems (col. 8, lines 24-25; col. 21, lines 33-34; col. 22, lines 30-33). Brent et al do not explicitly disclose MUC1 or beta-catenin; however, Brent et al do disclose that the "bait" and "prey" proteins may be chosen from any protein of interest, including proteins of unknown, known or suspected therapeutic or pharmacological importance such as oncoproteins or the cytoplasmic portions of membrane-associated receptors, or signaling proteins (col. 10, lines 38-50). Brent et al disclose, for example, the identification of Cdk2-interacting peptide aptamers, wherein Brent et al suggest that these peptide aptamers may be used in competition experiments (col. 18, lines 29-34).

It would have been obvious to one of ordinary skill in the art to modify the method of Brent et al to comprise a MUC1 test agent, a peptide fragment of a tumor progressor, and a tumor progressor test agent, wherein the tumor progressor is beta catenin, with a reasonable chance of success because Brent et al teach methods of identifying antagonist compounds that inhibit the protein interaction between two proteins of interest, the motivation being that Brent et al suggest that the method is useful for any desired protein(s). Absent evidence to the contrary, nothing non-obvious is seen with replacing the exemplary proteins of Brent et al with the artisan's desired proteins because Brent et al motivate the artisan to use the inventive method for each artisan's specific proteins of interest.

Thus, the invention as a whole is *prima facie* obvious.

Conclusion

9. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kevin K. Hill

Q. JANICE LI, M.D.
PRIMARY EXAMINER